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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/297,090	07/09/1999	STEFAN LANGE	REF/970230/L	9256

7590

07/02/2003

BACON & THOMAS
625 SLATERS LANE 4TH FLOOR
ALEXANDRIA, VA 223141176

EXAMINER

WANG, SHENGJUN

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 07/02/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/297,090

Applicant(s)

GORANSSON ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,33,34 and 41-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26,33,34 and 41-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on April 10, 2003 has been entered.

Claim Rejections 35 U.S.C. 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 26, 28, 30, 31, 42, 43, 45, 46, 49, 50, 52, 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnston (U.S. Patent 5,565,225), in view of the fact about malted cereal disclosed in Witt et al. (US 4,241,183, of record).

Johnston teaches a method for preventing diarrhea of young animal by feeding the animal a food product prepared from malted grain, particularly, malted barley. See, the abstract. A method of preventing diarrhea is seen to the skill the artisan to possess the process of regulating the flux of fluid and electrolyte in the intestine. The method herein would be considered inherently possess the limitation "1 ml of blood of said animal will contain at least 0.5 units of antisecretory proteins." Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389

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(BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to treating or preventing a malady or disease with old and well known compounds or compositions. It is now well settled law that administering compounds inherently possessing a therapeutic utility anticipates claims directed to such therapeutic use. Arguments that such therapeutic use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975)." In the instant application, Applicants' failure to distance the proffered claims from the anticipated therapeutic utility, renders such claims anticipated by the prior inherent use. As to the enzymatic activity, Witt et al. teach that it is well known that malted cereal contain enzyme and are widely used in food products. See, column 1, lines 5-10. Therefore, the food product employed by Johnson does have enzymatic activity since it contains malted cereals.

Claim Rejections 35 U.S.C. – 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

~~33,34,41-~~

4. Claims 26-[^]55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston (US 5,565,225) in view of Lange et al. (U.S. 5,296,243), and in further view of Robbins et al. (CAPlus abstract, AN 1972:111657), Aspinal et al. (Caplus abstract, AN 1956:30292), and Witt et al. (US 4,241,183, of record).

Johnston teaches a method for preventing diarrhea of young animal by feeding the animal a food product prepared from malted grain, particularly, malted barley. A similar method may also applied to human. See, particularly, the abstract. A method of preventing diarrhea is seen to the skill the artisan to possess the process of regulating the flux of fluid and electrolyte in the intestine.

Johnston does not teach expressly to increase the ASP in the animal blood to 0.5 unit/ml.

However, Lange teaches a method for regulating flux fluid and electrolyte in the intestine of an animal and reducing diarrhea in animal comprising administering to the animal a food enriched in amino acid and sugars and or amino acids. The method leads to an APS concentration of greater than 0.5 unit/ml in the animal blood. See, the abstract, table VI and table VIII in column 5 and 6, and the claims. Robbins et al and Aspinal et al teaches that malted grain are known to be rich in amino acids and sugars. See the abstract.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the method of Johnston for regulating the flux of fluid and electrolyte in the intestine of an animal so that 1 ml blood of said animal will contain at least 0.5 unit of ASP because Johnston's method is known to preventing diarrhea and is known to containing the active ingredients of Lange, i.e., amino acid and sugar, and food

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composition containing amino acid and sugar useful for preventing diarrhea is known to increase the concentration of ASP in the said animal blood. Further more, any common grain, including barley, wheat, corn, or rice, would have been expected to be similarly useful in Johnston's method. As to the enzymatic activity, Witt et al. teach that it is well known that malted cereal contain enzyme and are widely used in food products. See, column 1, lines 5-10. Therefore, the food product employed by Johnson does have enzymatic activity since it contains malted cereals.

5. ^{33,34,41-} Claims 26-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolles et al. (US 4,834,989) and Camburn (US 5,552,175) in view of Witt et al. (US 4,241,183).

Bolles et al. teach a flaked cereal and the method of making the same. The method comprising employing products having enzymatic activity, such as malted wheat, malted barley or malted sorghum. See, the abstract, column 3, lines 47-53, column 24-39. Camburn further teach a powdered foodstuff prepared with malted cereals. See, the examples in columns 6-9.

The primary references do not teach expressly a method for regulating the flux of fluid and intestine of human so that 1 ml of blood will contain at least 0.5 units of ASP.

However, people who consume the food containing malted grain would have reasonably expected to have ASP level more than 0.5unit/ml, absent evidence to the contrary. Witt et al. further teach that it is well known that malted cereal contain enzyme and are widely used in food products. See, column 1, lines 5-10.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to let people consume the food product of malted cereal in the product of Bolles et al and Camburn (US 5,552,175) or food product contain some of malted cereal as suggested by Witt. The instant claims are directed to affecting a biochemical

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pathway with an old and well-known composition. It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to *In re Swinehart*, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." Additionally, where the patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, (i.e., consuming food product containing malted cereal), albeit distanced by various biochemical intermediates. The ultimate utility for the claimed composition is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

Response to the Arguments

Applicants' amendments and remarks submitted April 10, 2003 have been fully considered, but are not persuasive for reasons discussed below.

Applicants traverse the rejection under 35 U.S.C 102 over Johnston on the ground that Johnston particularly teach for treatment of allergy induced diarrhea and the instant claims are generic to all diarrhea. It is noted that a claim is anticipated if any species encompassed by the

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claim is anticipated. Note the claimed method is directed to regulation of the flux of fluid and electrolytes in the intestine, which is what Johnston's method does.

6. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the detailed difference of the foodstuff between those disclosed in the references and herein in the specification, or the process of making the same) are not recited in the rejected claim(s).

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants are in error in stating that Johnston's only employ 1% of malted barley. In fact, Johnston's claimed a wide of malted cereals (0.25-50% of the weight of other materials, see the claims). In examples the amounts of malted barley employed are in the range of 10% by dry weight (examples 1, 2, , 12-14) to 2% by dry weight (examples 3-10). See, e.g., column 4, lines 62-63. They are the amounts herein employed.

7. Applicants mention that "there are great technical problems in preparing food stuff with malt (except beer) in order for them to be palatable or suitable for industrial methods of preparation". However, Johnston teaches the employment of foodstuff prepared from malted grain, particularly, malted barley. Instant claims do not have any limitation with respect to the composition employed in the method which would distinct the composition from prior art. Also, Bolles et al., Camburn, and Witt et al. teach that malted cereals are widely employed in food industry. Furthermore, applicants do not disclose, or limited the claims to, a particular food product which would be distinct from prior art.

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In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the teaching suggestion and motivation are found both in the cited references, and the knowledge generally available to one of ordinary skill in the art. Particularly, Johnston's teaches that composition comprising malted cereals are particularly useful for preventing a diarrhea (regulating the of the flux of fluid and electrolytes in the intestine), Johnston's does not teach expressly to increase the ASP in the animal blood to 0.5 unit/ml. However, the secondary references teaches that malted cereals contains amino acids and glucoses, and composition containing amino acid and glucose is known to increase the ASP in the animal blood. Therefore, it would have been prima facie obvious to employ a composition containing malted cereals to increase ASP in the animal blood.

Applicants assert that the rejection under 35 U.S.C. 103 over Bolles et al. and Camburn in view of Witt et al. is improper because the cited reference do not teach a food having enzymatic activity. Particularly, applicants have suggested that the process of making the foodstuff disclosed in Bolles would destroy the enzymatic activity in malted cereals. However, the examiner found no factual evidence in supporting such allegation. Particularly, Bolles teach to increase temperature to *deactivate* the enzymatic activity, not to *destroy* the enzymatic activity (see the claims). Further, the cooking temperature employed by Boller is about 260 °F (see

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example 1), which is common cooking temperature. Since applicants do not disclose the specific process for making the "*bread*" employed in the example (see pages 5-7 in the specification), it is assumed that the "*bread*" is made by a normal process commonly employed in the art.

For reasons discussed above, the claimed invention has been properly rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner

SHENGJUN WANG
PATENT EXAMINER

Shengjun Wang

June 28, 2003